OCT 15 2007

stryker Howmedica OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

510(k) Summary of Safety and Effectiveness for the Triathlon® TS Knee System

Proprietary Name:	Triathlon® TS Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. 21 CFR §888.3560
Regulatory Class:	Class II
Device Product Code:	87 JWH - prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5612 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	August 8, 2007

Device Description

The Triathlon TS Total Knee System features TS and TS Plus tibial inserts available in sizes 1 through 8 and thicknesses from 9mm to 31mm. These tibial inserts used with the Triathlon TS Total Knee System have been modified. The tibial inserts feature an open cam box with a tibial post slot to accommodate a cobalt chrome tibial post intended for additional stability in the knee joint. The Triathlon TS tibial inserts also feature a metal locking wire for assembly into

previously cleared Triathlon tibial baseplates. The Triathlon TS Plus and the Triathlon TS inserts are available in sequentially crosslinked and standard polyethylene.

Intended Use:

The Triathlon TS Total Knee System tibial components are intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. All tibial components presented in this submission are provided sterile for single-use.

Indications for Use

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques

Additional Indications for Posterior Stabilized (PS) and Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

Additional Indications for Total Stabilizer (TS) Components:

- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

The Triathlon TS Total Knee System components are intended for cemented use only.

Substantial Equivalence:

The determination of substantial equivalence of the Triathlon TS Total Knee System tibial inserts is based on its similarities in indications for use, intended use, design and sterilization to Howmedica Osteonics' Triathlon TS Total Knee System (K070095, cleared June 01, 2007).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Howmedica Osteonics Corp.
% Ms. Tiffani Rogers
Regulatory Affairs Specialist
Stryker Orthopaedics
325 Corporate Drive
Mahwah, New Jersey 07432

OCT 15 2007

Re: K072221
Trade/Device Name: Triathlon® TS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: September 27, 2007
Received: September 28, 2007

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

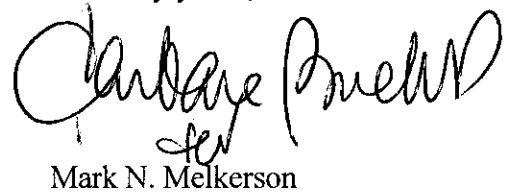
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K072221

Device Name: Triathlon® TS Knee System

Indications for Use

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Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucchi for MJM

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

K072221

510(k) Number K072221 BDB